Auxiliary stability study 091, month 18 stability tables and interim report. A copy of the protocol and all protocol arnendments to date has also been included for reference.

The results obtained to date from the stability studies substantiate the proposed expiry dating ______; for the drug product in all three fill sizes, 7.5 g, 42 g, 77 g when stored at controlled room temperature between 15° - 25°C (59° - 77°F).

Reference is also made to CMC volume 1.4, page 002. The following updated packaging components DMF letters are included, which are addressed

Please let me know if you have any questions about the enclosed information.

Sincerely,

Robert J. McCormack, Ph.D. Vice President, Regulatory Affairs

APPEARS THIS WAY ON ORIGINAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, 314 & 601)

FORM FDA 356h (4/97)

Form Approved: OMB No. 0910-0338 Expiration Date: April 30, 2000 See OMB Statement on last page.

FOR FDA USE ONLY
APPLICATION NUMBER

LICANT INFORMATION NAME OF APPLICANT DATE OF SUBMISSION Clindagel, LLC April 28, 2000 TELEPHONE NO. (Include Area Code) FACSIMILE (FAX) Number (Include Area Code) (707) 793-0145 (707) 793-2600 AUTHORIZED U.S. AGENT NAME & ADDRESS (Number, Street, APPLICANT ADDRESS (Number, Street, City, State, Country, ZIP Code or City, State, ZIP Code, telephone & FAX number) IF APPLICABLE Mail Code, and U.S. License number if previously issued): Robert J. McCormack, Ph.D. 4189 Chaparral Court **Target Research Associates** Santa Rosa, CA 95409 554 Central Avenue New Providence, NJ 07974 Telephone: 908-464-7500 Fax: 908-464-3529 PRODUCT DESCRIPTION NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (IF PROPERTY OF A PROPRIETARY NAME (trade name) IF ANY ESTABLISHED NAME (e.g., Proper name, USP/USAN name) 1% Clindamycin Phosphate, USP Clindagel CODE NAME (If an CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (If any) Clindamycin 2-(dihydrogen phosphate) ROUTE OF ADMINISTRATION: STRENGTHS: DOSAGE FORM: 1% dindamycin phosphate Topical Topical gel 'PROPOSED) INDICATION(S) FOR USE: Once a day treatment of acne vulgaris LICATION INFORMATION APPLICATION TYPE ☐ ABBREVIATED APPLICATION (ANDA, AADA, 21 CFR 314.94) M NEW DRUG APPLICATION (21 CFR 314.50) (check one) BIOLOGICS LICENSE APPLICATION (21 CFR part 601) **⊠** 505 (b) (2) **507** IF AN NDA. IDENTIFY THE APPROPRIATE TYPE 505 (b) (1) IF AN ANDA, OR AADA, IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION Holder of Approved Application Name of Drug-TYPE OF SUBMISSION ☐ RESUBMISSION ORIGINAL APPLICATION T-AMENDMENT TO A PENDING APPLICATION (check one) STABLISHMENT DESCRIPTION SUPPLEMENT ☐ SUPAC SUPPLEMENT ☐ PRESUBMISSION ANNUAL REPORT ☐ CHEMISTRY, MANUFACTURING AND CONTROLS SUPPLEMENT ☑ OTHER ☐ EFFICACY SUPPLEMENT ☐ LABELING SUPPLEMENT REASON FOR SUBMISSION Submission of updated stability data OVER THE COUNTER PRODUCT (OTC) PRESCRIPTION PRODUCT (Rx) PROPOSED MARKETING STATUS (check one) THIS APPLICATION IS ☐ PAPER ☐ PAPER AND ELECTRONIC ☐ ELECTRONIC NUMBER OF VOLUMES SUBMITTED ESTABLISHMENT INFORMATION Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at this site. Please indicate whether the site is ready for inspection or, if not, when it will be ready. See Attachment Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application) See Attachment

This application contains the following items: (Check all that apply)						
1105	1.	Index	. (Спеск ан шас арргу)			
	2.	Labeling (check one)	☐ Draft Labeling	Final Printed Labeling		
	3.	Summary (21 CFR 314.50 (c))			<u></u>	
-	4.	Chemistry section				
		A. Chemistry, manufacturing, a	nd controls information (e.g.	21 CFR 314.50 (d) (1), 21	CFR 601.2)	
-		B. Samples (21 CFR 314.50 (e				
		C. Methods validation package				
	5.	Nonclinical pharmacology and		··· · · · · · · · · · · · · · · · · ·	601.2)	
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	8.	Clinical data section (e.g. 314.				·
	9.	Safety update report (e.g. 21 C		CFR 601.2)		
	10.	Statistical section (e.g. 21 CFR				
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	Targe 554 C	treet, City, State, and ZIP Code) It Research Associates Central Avenue Providence, NJ 079747			Telephone Number (908) 464-7	7500

Public reporting burden for this collection of information is estimated to average 40 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

DHHS, Reports Clearance Officer Paperwork Reduction Project (0910-0338) Hubert H. Humphrey Building, Room 531-H 200 Independence Avenue, S.W. */ashington, DC 20201

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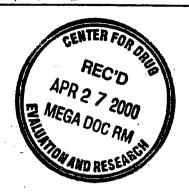




CLINICAL RESEARCH, REGULATORY AFFAIRS & BIOSTATISTICS

April 26, 2000

Jonathan Wilkin, MD
Director,
Division of Dermatologic and Derital Drug Products
Food and Drug Administration
9201 Corporate Boulevard
North 214
Rockville, MD 20850



NDA ORIG AMENDMENT

RE:

NDA 50-782

Clindagel, LLC, Santa Rosa, CA

Clindagel™ (Clindamycin Phosphate — l gel), 1% Indication: Once a day treatment of acne vulgaris

NDA amendment – submission of dermal absorption study report

Dear Dr. Wilkin:

Reference is made to NDA 50-782, for Clindagel™ (Clindamycin Phosphate gel), 1% for the once a day treatment of acne vulgaris which was submitted on January 27, 2000 and to the commitment, made by Clindagel, LLC, which appears in Vol. 1.1 page 019 and Vol. 1.17 page 002 of the original application.

In the above referenced commitment statement, Clindagel, LLC, agreed to submit within 3 months of filing the NDA, an amendment containing the final report of the dermal absorption study requested by FDA at the pre-NDA meeting.

Therefore, on behalf of Clindagel, LLC, we are submitting in duplicate, the final report for study CGEL-035 entitled "An Open-Label Randomized Study of the Comparative Absorption of Clindagel™ (QD) versus Cleocin T (BID) in Subjects with Acne Vulgaris". In addition, we are also submitting an updated package insert, human pharmacokinetic and bioavailability summary and clinical pharmacology summary which incorporate the results obtained from the CGEL-005 study.

Please let me know if you have any questions about the enclosed information.

Sincerely,

Robert J. McCormack, Ph.D.

Vice President, Regulatory Affairs

ORIGINAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN

ANTIBIOTIC DRUG FOR HUMAN USE

Form Approved: OMB No. 0910-0338 Expiration Date: April 30, 2000 See OMB Statement on last page.

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(Title 21, Code of Federal Regulations, 314 & 601)

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NAME OF APPLICANT			BMISSION		
Clindagel, LLC			il 26, 2000		
TELEPHONE NO. (Include Area Code) (707) 793-2600		FAX) Number (Include Area Code) 7) 793-0145			
APPLICANT ADDRESS (Number, Street, City, State, Co Mail Code, and U.S. License number if previously issued	ountry, ZIP Code or All d): All	UTHORIZED U.S. ity, State, ZIP Code	AGENT NAME & ADDRESS Sireet, e, telephone & FAX number 1997		
4189 Chaparral Court Santa Rosa, CA 95409	Robert J. McC	Cormack, Ph.D. rch Associates venue lice, NJ 07974 08-464-7500			
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NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER,	OR BIOLOGICS LICENSE	ADDI ICATIONI N	I IMPED (If proviously issued) 51		
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1% Clindamycin Phosphate, USP	Clindagel	TVAINE (I/OOC HOI/			
CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (Clindamycin 2-(dihydrogen phosphate)	(If any)		CODE NAME (If any)		
	ENGTHS:		ROUTE OF ADMINISTRATION:		
	1% clindamycin phosphate	·	Topical		
(PROPOSED) INDICATION(S) FOR USE: Once a day treatment of acne vulgaris			-		
PLICATION INFORMATION					
APPLICATION TYPE					
(check one)	CFR 314.50) APPLICATION (21 CFR page 2)		ICATION (ANDA, AADA, 21 CFR 314.94)		
IF AN NDA, IDENTIFY THE APPROPRIATE TYPE	☐ 505 (b) (1) 🛛		507		
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REASON FOR SUBMISSION			.1		
Submission of additional study results and updated		beling, Clinical Pha	armacology, Pharmacokinetics/Bioavailability)		
PROPOSED MARKETING STATUS (check one)	FRESCRIPTION PRODUCT	(Rx) □ OV	ER THE COUNTER PRODUCT (OTC)		
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Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at this site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.					
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FORM FDA 356h (4/97)					

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	1.	Index
. X	2.	Labeling (check one) Draft Labeling Final Printed Labeling
	3.	Summary (21 CFR 314.50 (c))
	4.	Chemistry section
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		B. Samples (21 CFR 314.50 (e) (1), 21 CFR 601.2 (a)) (Submit only upon FDA's request)
		C. Methods validation package (e.g. 21 CFR 314.50 (e) (2) (i), 21 CFR 601.2)
	5.	Nonclinical pharmacology and toxicology section (e.g. 21 CFR 314.50 (d) (2), 21 CFR 601.2)
Х	6.	Human pharmacokinetics and bioavailability section (e.g. 21 CFR 314.50 (d) (3), 21 CFR 601.2)
·	7.	Clinical Microbiology (e.g. 21 CFR 314.50 (d) (4))
х	8.	Clinical data section (e.g. 314.50 (d) (5), 21 CFR 601.2)
	9.	Safety update report (e.g. 21 CFR 314.50 (d) (5) (vi) (b), 21 CFR 601.2)
	10.	Statistical section (e.g. 21 CFR 314.50 (d) (6), 21 CFR 601.2)
	11.	
	12.	Case report forms (e.g. 21 CFR 314.50 (f) (2), 21 CFR 601.2)
	13.	Patent information on any patent which claims the drug (21 U.S.C. 355 (b) or (c))
	14.	A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b) (2) or (j) (2) (A))
	15	Establishment description (21 CFR Part 600, if applicable)
***	16.	Debarment certification (FD&C Act 306 (k)(1))
	17.	Field copy certification (21 CFR 314.5 (k) (3))
	18.	User Fee Cover Sheet (Form FDA 3397)
	19.	OTHER (Specify)
CERT	IFICA	TION
precai	utions oplicat	pdate this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If it is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to g:

1. Good manufacturing practice regulations in 21 CFR 210 and 211, 606, and/or 820.

2. Biological establishment standards in 21 CFR Part 6()0.

Labeling regulations in 21 CFR 201, 606, 610, 660 and/or 809.

4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR 202.

5. Regulations on making changes in application in 21 CFR 314.70, 314.71, 314.72, 314.97, 314.99, and 601.12.

6. Regulations on reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.

7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

Warning: a willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT TYPELI NAME AND TITLE

Robert J. McCormack, Ph.D. Vice President, Regulatory Affairs

Target Research Associates

DATE

April 26,2000

ADDRESS (Street, City, State, and ZIP Code) **Target Research Associates**

554 Central Avenue

New Providence, NJ 079747

Telephone Number

(908) 464-7500

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FORM FDA 356h (4/97)



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CLINICAL RESEARCH, REGULATORY AFFAIRS & BIOSTATISTICS

March 24, 2000

Jonathan Wilkin, MD
Director,
Division of Dermatologic and Dental Drug Products
Food and Drug Administration
9201 Corporate Boulevard
North 214
Rockville, MD 20850

RE: NDA 50-782

Clindagel, LLC, Santa Rosa, CA

Clindagel™ (Clindamycin Phosphate — gel), 1% Indication: Once a day treatment of acne vulgaris

Request for additional information

Dear Dr. Wilkin:

Reference is made to NDA 50782, for Clindagel™ (Clindamycin Phosphate —— I gel), 1% for the once a day treatment of acne vulgaris submitted on January 27, 2000, and the March 21, 2000 telephone request of Ms. Indira Kumar.

On behalf of Clindagel, LLC, we are submitting in duplicate the following information requested by Ms. Kumar on behalf of the reviewing statistician:

- An electronic version of the Phase III Integrated Clinical and Statistical Report (CGEL-003) in version Word 97
- A diskette labeled CGEL-003 Data Files which contains one zipped file of data in SAS for Windows v. 6.12
- A diskette labeled CGEL-003 Table and Listing Programs which contains one zipped file of programs in SAS for Windows v.6.12
- A copy of the statistical analysis plan for the CGEL-003 study

Please let me know if you have any questions about the enclosed information.

Sincerely,

Robert J. McCormack, Ph.D.

Vice President, Regulatory Affairs

ORIGINAL

554 Central Avenue • New Providence, NJ 07974 USA • 908/464-7500 • XAX: 908/464-7515



DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN

ANTIBIOTIC DRUG FOR HUMAN USE (Title 21, Code of Federal Regulations, 314 & 601) Form Approved: OMB No. 0910-0338 Expiration Date: April 30, 2000 See OMB Statement on last page.

FOR FDA USE ONLY
APPLICATION NUMBER

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NAME OF APPLICANT	DATE OF SUBM	SSION	1100			
Clindagel, LLC			24, 2000	MAR 2 7 2000		
TELEPHONE NO. (Include 1 O. 1.)				LOUY		
TELEPHONE NO. (Include Area Code) (707) 793-2600) Number (Included)	MEGA-DOC AM		
(101) 193-2000		(/0/) 7	93-0145			
APPLICANT ADDRESS (Number, Street, City, State,	Country, ZIP Code or	AUTHORIZED U.S. AG	ENT NAME & ADDIM	A manage track		
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4189 Chaparral Court		Robert J. McCorr				
Santa Rosa, CA 95409		Target Research		•		
		554 Central Aven New Providence,				
		Telephone: 908-		. .		
		Fax: 908-464-35		•		
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This a	oplica	ation contains the following items:	(Check all that apply)	· · · · · · · · · · · · · · · · · · ·			
	1.	Index					
	2.	Labeling (check one)	☐ Draft Labeling	☐ Final Printed Labeling			
	3.	Summary (21 CFR 314.50 (c))	•				
	4.	Chemistry section					
		A. Chemistry, manufacturing, an	d controls information (e.g	. 21 CFR 314.50 (d) (1), 21 CFR 601.2)			
. –		B. Samples (21 CFR 314.50 (e)	(1), 21 CFR 601.2 (a)) (Su	bmit only upon FDA's request)	· · · · · · · · · · · · · · · · · · ·		
		C. Methods validation package (e.g. 21 CFR 314.50 (e) (2)	(i), 21 CFR 601.2)			
	5.	Nonclinical pharmacology and to	oxicology section (e.g. 21 C	FR 314.50 (d) (2), 21 CFR 601.2)			
	6.	Human pharmacokinetics and bi	ioavailability section (e.g. 2	1 CFR 314.50 (d) (3), 21 CFR 601.2)			
	7.	Clinical Microbiology (e.g. 21 CF	R 314.50 (d) (4))				
	8.	Clinical data section (e.g. 314.50) (d) (5), 21 CFR 601.2)				
	9.	Safety update report (e.g. 21 CF	R 314.50 (d) (5) (vi) (b), 21	CFR 601.2)	·		
	10.	Statistical section (e.g. 21 CFR:	314.50 (d) (6), 21 CFR 601	.2)	•		
	11.	Case report tabulations (e.g. 21					
	12.	Case report forms (e.g. 21 CFR	314.50 (f) (2), 21 CFR 601	.2)			
_	13.						
	14.			s the drug (21 U.S.C. 355 (b) (2) or (j) (2)	(A))		
	15.						
	16.	Debarment certification (FD&C A			· · · · · · · · · · · · · · · · · · ·		
		Field copy certification (21 CFR			·		
		User Fee Cover Sheet (Form FD			•		
х		OTHER (Specify) FDA reques					
CERTI			t to additional smorthation	•			
precau this ap he foll 1.	tions plicat owing Goo	, or adverse reactions in the draft ion is approved, I agree to comply p: d manufacturing practice regulation	labeling. I agree to submit with all applicable laws ar ons in 21 CFR 210 and 211	product that may reasonably affect the state safety update reports as provided for by diregulations that apply to approved appliance, 606, and/or 820.	regulation or as requested by FDA. If		
		ogical establishment standards in eling regulations in 21 CFR 201, 6		·			
4.	In th	e case of a prescription drug or bi	iological product, prescripti	on drug advertising regulations in 21 CFR	202.		
		ulations on making changes in ap ulations on reports in 21 CFR 314		, 314.71, 314.72, 314.97, 314.99, and 601	.12.		
7.	Loca	al, state and Federal environmenta	al impact laws.	·	-		
If this a	pplic	ation applies to a drug product that	at FDA has proposed for so	heduling under the Controlled Substances	s Act I agree not to market the		
produc	t until ta an	I the Drug Enforcement Administration in this submission by	ation makes a final schedu	ling decision. the best of my knowledge are certified to	he true and accurate		
		willfully false statement is a crimin			be tide and accurate.		
SIGNAT	URE	OF RESPONSIBLE OFFICIAL OR AGI			DATE .		
				lcCormack, Ph.D. ent, Regulatory Affairs	March 24,2000		
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IM	JU	A I TOULUCK	()		· ·		
		treet, City, State, and ZIP Code)		Telephone Num	ber		
		t Research Associates entral Avenue		(908)46			
		Providence, NJ 079747		(300)40			
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Public	Public reporting burden for this collection of Information is estimated to average 40 hours per response, including the time for reviewing						
instruct	ions.	searching existing data sources,	gathering and maintaining	the data needed, and completing and review	ewing the collection of information.		
sena c	omme	ents regarding this burden estima	te or any other aspect of th	is collection of information, including sugg	estions for reducing this burden to:		

DHHS, Reports Clearance Officer Paperwork Reduction Project (0910-0338) Hubert H. Humphrey Building, Room 531-H 200 Independence Avenue, S.W. Washington, DC 20201 An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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FORM FDA 356h (4/97)



WITHHOLD 2 PAGE (S)

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THIS SECTION WAS DETERMINED NOT TO BE RELEASABLE

14 pages



CLINICAL RESEARCH, REGULATORY AFFAIRS & BIOSTATISTICS

February 29, 2000

NEW CORRESP

NC

Jonathan Wilkin, MD
Director,
Division of Dermatologic and Dental Drug Products
Food and Drug Administration
9201 Corporate Boulevard
North 214
Rockville, MD 20850



RE: Clindagel, LLC, Santa Rosa, CA

Clindagel™ (Clindamycin Phosphate ____ gel), 1% Indication: Once a day treatment of acne vulgaris

Request for additional information

Dear Dr. Wilkin:

Reference is made to NDA for Clindagel™ (Clindamycin Phosphate gel), 1% for the once a day treatment of acne vulgaris submitted on January 27, 2000, and the February 28, 2000 telephone request of Ms. Kalyani Bahatt on behalf of Dr. James Vidra.

On behalf of Clindagel, LLC, we are amending to include the statement that clindamycin phosphate has indicated This statement was inadvertently omitted in the original NDA submission. The 356h establishment information has been corrected to reflect the addition

Please let me know if you have any questions about the enclosed information.

DUNQUE

Sincerely,

Robert J. McCormack, Ph.D.

Vice President, Regulatory Affairs

ORIGINAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, 314 & 601)

Form Approved: OMB No. 0910-0338 Expiration Date: April 30, 2000 See OMB Statement on last page.

FOR FDA USE ONLY
APPLICATION NUMBER

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PLICANT INFORMATION NAME OF APPLICANT				CENTER	
Clindagel, LLC			DATE OF SUB Febr	BMISSION Puary 29, 2000 MAR 0.3 2000	
TELEPHONE NO. (Include Area Code) (707) 793-2600				AX) Number (Inc. Co Area Code)) 793-0145 MEGA	
APPLICANT ADDRESS (Number, Street, City, St. Mail Code, and U.S. License number if previously	ate, Country, ZIP Co		 HORIZED U.S. A : State. ZIP Code	AGENT NAME & ADDRESS (Number Speet)	
4189 Chaparral Court Santa Rosa, CA 95409			Robert J. McCo Target Researd 554 Central Av New Providence Telephone: 90	ch Associates venue ce, NJ 07974 08-464-7500	
-		l	Fax: 908-464-	3529	
PRODUCT DESCRIPTION					
NEW DRUG OR ANTIBIOTIC APPLICATION NUM ESTABLISHED NAME (e.g., Proper name, USP/U					
1% Clindamycin Phosphate, USP	(SAN name)	Clindagel	IAME (trade name	e) IF ANY	
CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT N Clindamycin 2-(dihydrogen phosphate)	IAME (If any)	· · · · · · · · · · · · · · · · · · ·		CODE NAME (If any)	
DOSAGE FORM:	STRENGTHS:			ROUTE OF ADMINISTRATION:	
Topical gel 'ROPOSED) INDICATION(S) FOR USE:	1% clindamyc	in phosphate		Topical	
Once a day treatment of acne vulgaris				•	
				-	
APPLICATION INFORMATION APPLICATION 1YPE				·	
(check one) NEW DRUG APPLICATIO	N (21 CFR 314.50) ENSE APPLICATION	ABBR (21 CFR part	EVIATED APPLIC	CATION (ANDA, AADA, 21 CFR 314.94)	
IF AN NDA, IDENTIFY THE APPROPRIATE TYPE	505 (b)) (1) 🛛 5	05 (b) (2)	507	
IF AN ANDA, OR AADA, IDENTIFY THE REFERE Name of Drug	NCE LISTED DRUG Holde	G PRODUCT Ti er of Approved	HAT IS THE BAS Application	IS FOR THE SUBMISSION	
TYPE OF SUBMISSION -			· · · · · · · · · · · · · · · · · · ·		
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PRESUBMISSION ANNUAL REPORT	∐ ESTABL	LISHMENT DESC	CRIPTION SUPPLEM	MENT	
☐ EFFICACY SUPPLEMENT ☐ LABELING SI	UPPLEMENT C	HEMISTRY, MAN	UFACTURING AND	CONTROLS SUPPLEMENT	
REASON FOR SUBMISSION FDA request for additional information					
PROPOSED MARKETING STATUS (check one)	□ PRESCRIPTION □ PR	ON PRODUCT (F	x) □ OVE	ER THE COUNTER PRODUCT (OTC)	
NUMBER OF VOLUMES SUBMITTED N/A THIS APPLICATION IS ☐ PAPER ☐ PAPER AND ELECTRONIC ☐ ELECTRONIC					
ESTABLISHMENT INFORMATION					
Provide locations of all manufacturing, packaging and control sites for cirug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at this site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.					
See Attachment					
-				·	
oss References (list related License Applicati	ons, INDs, NDAs, P	PMAs, 510(k)s.	IDEs, BMFs, and	d DMFs referenced in the current application)	
See Attachment					
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This a	This application contains the following items: (Check all that apply)					
	1. Ir	ndex				
	2. L	abeling (check one) .	☑ Draft Labeling	Final Printed Labeling		
	3. S	Summary (21 CFR 314.50 (c))				
. —	4. C	Chemistry section				
	Α	. Chemistry, manufacturing, and	controls information (e.g. 2	21 CFR 314.50 (d) (1), 21	CFR 601.2)	
. –	В	3. Samples (21 CFR 314.50 (e) (1), 21 CFR 601.2 (a)) (Subr	nit only upon FDA's reque	est)	
	C	. Methods validation package (e	.g. 21 CFR 314.50 (e) (2) (), 21 CFR 601.2)		
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 	£	luman pharmacokinetics and bio				
		Clinical Microbiology (e.g. 21 CFF				
-		Clinical data section (e.g. 314.50				
		Safety update report (e.g. 21 CFF		CER 601 2)		•
		Statistical section (e.g. 21 CFR 3				
ļ		Case report tabulations (e.g. 21 C				
	L					
<u> </u>	1	Case report forms (e.g. 21 CFR 3				
	1	Patent information on any patent				
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	L	Debarment certification (FD&C Ac				
	17. F	field copy certification (21 CFR 3	14.5 (k) (3))			
	18. L	Jser Fee Cover Sheet (Form FD/	A 3397)			
X	19. C	OTHER (Specify) FDA request	for additional information			
precat this ap e fol 2 3 4 5 6 7 If this produ The d Warni	utions, copplication llowing: I. Good II. Good II. Biolog II. Labeli II. In the II. Regult II. Local, II. applicate the country and ing: a work of the country and ing.	ate this application with new safe or adverse reactions in the draft lands in is approved, I agree to comply manufacturing practice regulation ical establishment standards in 2 ng regulations in 21 CFR 201, 60 case of a prescription drug or bid ations on making changes in applications on reports in 21 CFR 314. State and Federal environmentation applies to a drug product that he Drug Enforcement Administration in this submission har illifully false statement is a crimine RESPONSIBLE OFFICIAL OR AGE	abeling. I agree to submit swith all applicable laws and as in 21 CFR 210 and 211, 21 CFR Part 600. 10, 610, 660 and/or 809. 11, 600.80, and 60 and 60 are set in a proposed for scheduling and a proposed for scheduling are been reviewed and, to the all offense, U.S. Code, title and offense, U.S. Code, title and offense, U.S. Code, title and offense and and a proposed for J. M. 11, 11, 12, 13, 14, 15, 15, 15, 15, 15, 15, 15, 15, 15, 15	safety update reports as pd regulations that apply to 606, and/or 820. In drug advertising regulations 114.71, 314.72, 314.97, 30.81. Ineduling under the Controlog decision. The best of my knowledge 18, section 1001.	provided for by regular approved applications in 21 CFR 202 314.99, and 601.12.	t I agree not to market the
	Target 554 Ce New Pr	Research Associates ntral Avenue ovidence, NJ 079747			(908) 464-7	·
Public	c report	ting burden for this collection earching existing data sources,	of information is estimated gathering and maintaining t	he data needed, and com	ipleting and reviewi	g the time for reviewing ng the collection of information.

Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions

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FORM FDA 356h (4/97)

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2 Pages



CLINICAL RESEARCH, REGULATORY AFFAIRS & BIOSTATISTICS

February 29, 2000

NEW CORRESP

Jonathan Wilkin, MD
Director,
Division of Dermatologic and Dental Drug Products
Food and Drug-Administration
9201 Corporate Boulevard
North 214
Rockville, MD 20850



RE:

Clindagel, LLC, Santa Rosa, CA

Clindagel™ (Clindamycin Phosphate — gel), 1% Indication: Once a day treatment of acne vulgaris

Request for additional information

Dear Dr. Wilkin:

On behalf of Clindagel, LLC, we are submitting duplicate electronic copies of the annotated and non-annotated Clindagel package insert as requested by Ms. Millie Wright.

Please let me know if you have any questions about the enclosed information.

Sincerely,

Robert J. McCormack, Ph.D.

Vice President, Regulatory Affairs

ORIGINAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, 314 & 601)

FORM FDA 356h (4/97)

Form Approved: OMB No. 0910-0338 Expiration Date: April 30, 2000 See OMB Statement on last page.

FOR	FDA	USE	ONL	٧

APPLICATION NUMBER

LICANT INFORMATION					147010
NAME OF APPLICANT			DATE OF SUBI	MISSION	10 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
Clindagel, LEC				ary 29, 2000	1 2000
TELEPHONE NO. (Include Area Code)			FACSIMILE (FA	X) Number (Includ	31.
(707) 793-2600		•		793-0145	
APPLICANT ADDRESS (Number, Street, City, St	late Country 7IP Co	ode or ALIT	HODIZED II S. A.	CENT NAME & A	DDRESS (Not be) Steel
Mail Code, and U.S. License number if previously					number) IF APPLICABLE
4189 Chaparral Court			Robert J. McCo	rmack Ph D	
Santa Rosa, CA 95409		Ì	Target Research		•
54.114.11550, 57.155705	-		554 Central Ave		
		l	New Providence		-
		-	Telephone: 908		
		· ·	Fax: 908-464-3		•
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		ĺ	,	•	
-			-		·
PRODUCT DESCRIPTION					
NEW DRUG OR ANTIBIOTIC APPLICATION NU	MBER, OR BIOLOG	ICS LICENSE	APPLICATION NU	MBER (If previous	sly issued)
ESTABLISHED NAME (e.g., Proper name, USP/0	USAN name) PF	ROPRIETARY N	AME (trade name) IF ANY	
1% Clindamycin Phosphate, USP		Clindagel		•	
CHEMICAL /DIOCHEMICAL /DLOOP OPODLICT	NARE (If and		· · · · ·	L CODE NAME (#	()
CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT N Clindamycin 2-(dihydrogen phosphate)	NAINE (II arry)			CODE NAME (#	rany)
Cililoanty citi 2-(citiyorogen phosphate)			•	1	
DOSAGE FORM:	STRENGTHS.	• • •		ROUTE OF ADM	AINISTRATION:
Topical gel		cin phosphate	•	Topical	WIND TO THOM:
PROPOSED) INDICATION(S) FOR USE:				1	
Once a day treatment of acne vulgaris					
PLICATION INFORMATION		-			-
APPLICATION TYPE					
(check one) NEW DRUG APPLICATIO				ATION (ANDA, AA	ADA, 21 CFR 314.94)
BIOLOGICS LIC	ENSE APPLICATION	N (21 CFR part	601)		
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IF AN ANDA, OR AADA, IDENTIFY THE REFERI				2 FOR THE SORY	MISSION
Name of Drug	, HOIC	der of Approved	Application]
TYPE OF SUBMISSION					
(check one) ORIGINAL APPLICATION	T AMENDMEN	IT TO A PENDING	APPLICATION	RESUBMISSIO	ON ·
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	OPPLEMENT C	MEMISTRY, MAN	OFACTORING AND	CONTROLS SUPPL	EMENT OTHER
REASON FOR SUBMISSION					
FDA request for additional information					
PROPOSED MARKETING STATUS (check one)		ION PRODUCT (F	b) ∐OVE	R THE COUNTER PE	RODUCT (OTC)
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NUMBER OF VOLUMES SUBMITTED N/A		IS APPLICATION	IS KAIPAPER L] PAPER AND ELEC	CIRONIC DELECTRONIC
ESTABLISHMENT INFORMATION			· · · · · · · · · · · · · · · · · · ·		
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name,					
address, contact, telephone number, registration number (CFN), DMF number, an	d manufacturing s	leps and/or type of te		
conducted at this site. Please indicate whether the site is	ready for inspection or,	if not, when it will	pe ready.		
See Attachment					
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. ross References (list related License Applicat	tions, INDs. NDAs.	PMAs, 510(k)s.	IDEs, BMFs, and	DMFs reference	d in the current application)
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I nis a		tion contains the following items: (Check all that apply)			
	<u>1.</u>	Index			
	2.	Labeling (check one)	ng .		
	3.	Summary (21 CFR 314.50 (c))			
	4.	Chemistry section			
		A. Chemistry, manufacturing, and controls information (e.g. 21 CFR 314.50 (d) (1),			
		B. Samples (21 CFR 314.50 (e) (1), 21 CFR 601.2 (a)) (Submit only upon FDA's red	uest)	•	
		C. Methods validation package (e.g. 21 CFR 314.50 (e) (2) (i), 21 CFR 601.2)			
	5.	Nonclinical pharmacology and toxicology section (e.g. 21 CFR 314.50 (d) (2), 21 CF	R 601.2)		
	6.	Human pharmacokinetics and bioavailability section (e.g. 21 CFR 314.50 (d) (3), 21	CFR 601.2)		
	7.	Clinical Microbiology (e.g. 21 CFR 314.50 (d) (4))			
	8.	Clinical data section (e.g. 314.50 (d) (5), 21 CFR 601.2)			
	9.	Safety update report (e.g. 21 CFR 314.50 (d) (5) (vi) (b), 21 CFR 601.2)			
	10.	Statistical section (e.g. 21 CFR 314.50 (d) (6), 21 CFR 601.2)			
	11.	Case report tabulations (e.g. 21 CFR 314.50 (f) (1), 21 CFR 601.2)			
	12.	Case report forms (e.g. 21 CFR 314.50 (f) (2), 21 CFR 601.2)			
	13.	Patent information on any patent which claims the drug (21 U.S.C. 355 (b) or (c))			
	14.	A patent certification with respect to any patent which claims the drug (21 U.S.C. 35	5 (b) (2) or (j) (2) (A)		
	15.	Establishment description (21 CFR Part 600, if applicable)		"	
	16.	Debarment certification (FD&C Act 306 (k)(1))			
	17.	Field copy certification (21 CFR 314.5 (k) (3))			
	18.	User Fee Cover Sheet (Form FDA 3397)			
X	19.	OTHER (Specify) FDA request for additional information			
CERTI					
precau this ap e foll 1. 2. 3. 4. 5. 7. If this a produc The da Warnii	tions plications plication Good Biolic Label In the Reg Reg Locapplic t until ta an	addate this application with new safety information about the product that may reasonal, or adverse reactions in the draft labeling. I agree to submit safety update reports as ion is approved, I agree to comply with all applicable laws and regulations that apply it displays an application of the product regulations in 21 CFR 210 and 211, 606, and/or 820. Each establishment standards in 21 CFR Part 600. Each gregulations in 21 CFR 201, 606, 610, 660 and/or 809. The ecase of a prescription drug or biological product, prescription drug advertising regulations on making changes in application in 21 CFR 314.70, 314.71, 314.72, 314.97 suitations on reports in 21 CFR 314.80, 314.81, 600.80, and 600.81. The product that FDA has proposed for scheduling under the Contact of the Drug Enforcement Administration makes a final scheduling decision. In this submission have been reviewed and, to the best of my knowledge willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.	provided for by regite approved applications in 21 CFR 202, 314.99, and 601.12.	ulation or as requested by FDA. If ons, including, but not limited to	
0.0,0,1,	0,12	Robert J. McCormack, Ph.D.			
R	D	Vice President, Regulatory Affairs Target Research Associates	··	February 29, 2000	
		treet, City, Slate, and ZIP Code) t Research Associates	Telephone Number		
		Pentral Avenue	(908)464-7	'500	
New Providence, NJ 079747					
				·	
instruct	lions,	rting burden for this collection of information is estimated to average 40 hours p searching existing data sources, gathering and maintaining the data needed, and co ents regarding this burden estimate or any other aspect of this collection of information	mpleting and reviewi	ng the collection of information.	
Paperv Hubert 20 Inc	vork i H. H leper	orts Clearance Officer Reduction Project (0910-0338) umphrey Building, Room 531-H idence Avenue, S.W. DC 20201 An agency may not conduperson is not required to r information unless it displayed	espond to, a collection	n of	

FORM FDA 356h (4/97)

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1 page



DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION			REQUEST FOR CONSULTATION			
*Division/Office): HFD-520 (Division of Anti Infective Drug 1cts)				FROM: HFD-540 (Division of Dermatologic and Dental Drug Products) Jonathan Wilkin, MD/Division Director		
DATE: February 2, 2000	IND NO.:		NDA NO.:	TYPE OF DOCUMENT: New NDA Submission	DATE OF DOCUMENT: 1-27-00	
NAME OF DRUG: Clindagel (clindamycin pho gel)	osphate 1%	PRIORITY	CONSIDERATION: Standard	CLASSIFICATION OF DRUG: Antibiotic	DESIRED COMPLETION DATE: May 2, 2000	
NAME OF FIRM: Clindage	I, LLC (US A	Agent: Tar	get Research Associate	es)		
			REASON FO	R REQUEST	·	
			I. GEN	NERAL		
□ NEW PROTOCOL □ PROGRESS REPORT □ NEW CORRESPONDENCE □ DRUG ADVERTISING □ ADVERSE REACTION REPORT □ MANUFACTURING CHANGE/ADDITION □ MEETING PLANNED BY				☐ LABELING REVISION ☐ ORIGINAL NEW CORRESPONDENCE ☐ FORMULATIVE REVIEW		
			II. BION	TETRICS		
STATIST TYPE A OR B NDA REVII END OF PHASE II MEETI CONTROLLED STUDIES TOCOL REVIEW IER:		ATION BRA	NCH	STATISTICAL APPLICATION BRANCH CHEMISTRY REVIEW PHARMACOLOGY BIOPHARMACEUTICS OTHER:		
	 _		III. BIOPHAF	RMACEUTICS		
☐ DISSOLUTION ☐ BIOAVAILABILTY STUD ☐ PHASE IV STUDIES	DIES			☐ DEFICIENCY LETTER RESPONSE ☐ PROTOCOL-BIOPHARMACEUTICS ☐ IN-VIVO WAIVER REQUEST		
			IV. DRUG E	XPERIENCE		
☐ PHASE IV SURVEILLAND ☐ DRUG USE e.g. POPULAT ASSOCIATED DIAGNOSI ☐ CASE REPORTS OF SPEC ☐ COMPARATIVE RISK AS	TION EXPOSU ES CIFIC REACTION	RE, ONS (List be	elow)	☐ REVIEW OF MARKETING EXPERIED SUMMARY OF ADVERSE EXPERIED POISON RISK ANALYSIS		
·			V. SCHENTIFIC I	NVESTIGATIONS	•	
	CLINIC	AL		□ PREC	LINICAL	
COMMENTS/SPECIAL INSTRUCTIONS: Attn: Tom Hassel/ADRA/ODE IV The Division is requesting a microbiology consult for this new NDA submission. When a reviewer is assigned, I will						
invite you and that reviewer to the filing meeting. Please let me know if I can be of further asistance. Thanks. Indira Kumar/Project Manager 301-827-2072						
Priginal NDA FD-540/Div. Files (FD-540/I. Kumar/J. V	/idra/W. DeC	amp		 ·		
SIGNATURE OF REQU	JESTER:	<u>}</u>	7-2-00	METHOD OF DELIVERY (Check	k one):	
SIGNATURE OF RECE	EIVER:			SIGNATURE OF DELIVERER:		

CLINDAGEL, LLC.

4189 Chaparral Court • Santa Rosa CA 95409 Phone: (707) 483-7489 • Fax: (707) 546-3058

January 5, 2000

Jonathan K. Wilkin, M.D., Director
Division of Dermatologic and Dental Drug Products (HFD-540)
Office of Drug Evaluation V
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20875

Re: Clindagel™ (clindamycin phosphate — I gel), 1%

Dear Dr. Wilkin:

Please be advised that Dr. Robert McCormack, V.P. of Regulatory Affairs at Target Research Associates, has been appointed the US Agent and, as such, will act on behalf of Clindagel, LLC with regard to all matters concerning Clindagel™. Henceforward, please address all future communications, including FDA correspondence concerning Clindagel-related matters, directly to Dr. McCormack at the following address:

Robert McCormack, Ph.D.
Target Research Associates, Inc.
554 Central Avenue
New Providence, NJ 07974
Phone: (908) 464-7500
Fax: (908) 464-3529

Sincerely yours,

Gordon J. Dow, Pharm.D. Managing Member Clindagel, LLC Telephone (707) 483-7489 FAX (707) 546-3058

APPEARS THIS WAY
ON ORIGINAL

cc: K. White, B. McCormack



CLINICAL RESEARCH, REGULATORY AFFAIRS & BIOSTATISTICS

Janúary 27; 2000

Jonathan Wilkin, MD
Director,
Division of Dermatologic and Dental Drug Products
Food and Drug Administration
9201 Corporate Boulevard
North 214
Rockville, MD 20850

RE: Clindagel, LLC, Santa Rosa, CA

Clindagel™ (Clindamycin Phosphate — gel), 1% Indication: Once a day treatment of acne vulgaris

Initial submission of NDA 21-230

Dear Dr. Wilkin:

Pursuant to paragraph 505(b)(2) of the Food, Drug, and Cosmetic Act and 21 CFR 314.50, we are, on behalf of Clindagel LLC, submitting in duplicate a New Drug Application, NDA for Clindagel™ (Clindamycin Phosphate gel), 1% for the once a day treatment of acne vulgaris.

This NDA contains, among other items, a single adequate and well-controlled clinical trial to support the acne vulgaris indication. The protocol design was discussed at both the pre-IND and End of Phase 2 meetings with FDA and evaluated the following treatment groups: Clindagel QD, Clindagel Vehicle QD, Clindagel BID, Clindagel Vehicle BID and Cleocin T BID. The results of the trial were discussed with FDA during the pre-NDA meeting and it was concluded that the data would support the filability of the application.

All of the available information requested at the pre-NDA meeting has been incorporated in the NDA. At the beginning of each technical data section is an introduction which describes the content and format of the section as well as a regulatory summary pertinent to that specific section of the application.

A completed Application to Market a New Drug for Human Use (form FDA 356h) is enclosed. Also enclosed, and agreed to at the pre-NDA meeting, is Clindagel LLC's

Pediatric Use Information has been provided in Volume 1.1. In addition, a completed User Fee Cover Sheet (form 3397) is included. User Fee I.D. 3885 has been assigned to the Clindagel™ NDA, and a check for the amount of \$285,740:90 has been transmitted electronically to the Food and Drug Administration at the address of Mellon Bank, Pittsburgh, PA.

After following the advice of the Division of Dermatologic and Dental Drug Products, we believe this Application to be complete for review by your staff and would look forward to discussing, informally, the status of your review in approximately 45 days.

Please let me know if you have any questions about the enclosed information.

Robert J. McCormack, Ph.D.

Vice President, Regulatory Affairs

APPEARS THIS WAY ON ORIGINAL



Number of Pages Redacted 2



Confidential, Commercial Information



DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, 314 & 601)

Form Approved: OMB No. 0910-0338 Expiration Date: April 30, 2000 See OMB Statement on last page.

FOR FDA	USE ONLY
APPLICATION NUMBER	
* Head	

APPLICANT INFORMATION					
NAME OF APPLICANT Clindagel, LLC		DATE OF SUBMISSION January 27, 2000			
TELEPHONE NO. (Include Area Code) (707) 793-2600				ACSIMILE (FAX) Number (Include Area Code) (707) 793-0145	
APPLICANT ADDRESS (Number, Street, City, Sta Mail Code, and U.S. License number if previously				GENT NAME & ADDRESS (Number, Street, , telephone & FAX number) IF APPLICABLE	
4189 Chaparral Court			Robert J. McCo	ormack, Ph.D.	
Santa Rosa, CA 95409		Target Research Associates			
·	•	554 Central Avenue New Providence, NJ 07974			
		1	Telephone: 908		
		ļ	Fax: 908-464-3		
		ļ		•••	
PRODUCT DESCRIPTION					
NEW DRUG OR ANTIBIOTIC APPLICATION NUM					
ESTABLISHED NAME (e.g., Proper name, USP/U 1% Clindamycin Phosphate, USP	Clinda		AME (trade name	9) IF ANT	
CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT N	AME (If any)			CODE NAME (If any)	
Clindamycin 2-(dihydrogen phosphate)	•				
DOSAGE FORM:	STRENGTHS:			ROUTE OF ADMINISTRATION:	
Topical gel	1% clindamycin phosp	hate	•	Topical	
PROPOSED) INDICATION(S) FOR USE: Once a day treatment of acne vulgaris			*		
Office a day treatment of acrie volgaris	<u>-</u>			•	
APPLICATION INFORMATION					
APPLICATION TYPE	1404 OED 044 FO		7.44TED ADDI (DATION (ANDA AADA O4 CED 244 O4)	
(check one) NEW DRUG APPLICATIO	N (21 CFR 314.50) ENSE APPL∣CATION (21 CF			CATION (ANDA, AADA, 21 CFR 314.94)	
IF AN NDA, IDENTIFY THE APPROPRIATE TYPI	E 505 (b) (1)	⊠ 50	05 (b) (2)] 507	
IF AN ANDA, OR AADA, IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION Name of Drug Holder of Approved Application					
TYPE OF SUBMISSION	·				
(check one) ORIGINAL APPLICATION	AMENDMENT TO A PE	ENDING	APPLICATION	RESUBMISSION	
PRESUBMISSION ANNUAL REPORT	SSTABLISHMEN	T DESC	RIPTION SUPPLE	_	
☐ EFFICACY SUPPLEMENT ☐ LABELING SUPPLEMENT ☐ CHEMISTRY, MANUFACTURING AND CONTROLS SUPPLEMENT ☐ OTHER					
REASON FOR SUBMISSION Original NDA					
PROPOSED MARKETING STATUS (check one)	PRESCRIPTION PROD	DUCT (R	×) DVE	ER THE COUNTER PRODUCT (OTC)	
NUMBER OF VOLUMES SUBMITTED	THIS APPLIC	ATION I	S 🖾 PAPER	PAPER AND ELECTRONIC ELECTRONIC	
ESTABLISHMENT INFORMATION			·		
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at this site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.					
See Attachment					
	a				
Cross References (list related License Applicat See Attachment	ions, INDs, NDAs, PMAs, 5	10(k)s,	IDEs, BMFs, an	d DMFs referenced in the current application)	

This application contains the following items: (Check all that apply)				
L X	_1	Index		
X	2.	Labeling (check one)		
X	3.	Summary (21 CFR 314.50 (c))		
X	4.	Chemistry section		
ı X		A. Chemistry, manufacturing, and controls information (e.g. 21 CFR 314.50 (d) (1), 21	CFR 601.2)	
		B. Samples (21 CFR 314.50 (e) (1), 21 CFR 601.2 (a)) (Submit only upon FDA's requ	est)	•
X		C. Methods validation package (e.g. 21 CFR 314.50 (e) (2) (i), 21 CFR 601.2)		
X	5.	Nonclinical pharmacology and toxicology section (e.g. 21 CFR 314.50 (d) (2), 21 CFR	601.2)	
X	6.	Human pharmacokinetics and bioavailability section (e.g. 21 CFR 314.50 (d) (3), 21 C	FR 601.2)	
	7.	Clinical Microbiology (e.g. 21 CFR 314.50 (d) (4))		
X	8.	Clinical data section (e.g. 314.50 (d) (5), 21 CFR 601.2)		
	9.	Safety update report (e.g. 21 CFR 314.50 (d) (5) (vi) (b), 21 CFR 601.2)		-
, _ X	10.	Statistical section (e.g. 21 CFR 314.50 (d) (6), 21 CFR 601.2)	 	
Х	11.	Case report tabulations (e.g. 21 CFR 314.50 (f) (1), 21 CFR 601.2)	-	
Х	12.	Case report forms (e.g. 21 CFR 314.50 (f) (2), 21 CFR 601.2)		
Х	13.	Patent information on any patent which claims the drug (21 U.S.C. 355 (b) or (c))		· · · · · · · · · · · · · · · · · · ·
	14.	A patent certification with respect to any patent which claims the drug (21 U.S.C. 355	(b) (2) or (j) (2) (A))
	15.	Establishment description (21 CFR Part 600, if applicable)		
Х	16.	Debarment certification (FD&C Act 306 (k)(1))		
Χ,	17.	Field copy certification (21 CFR 314.5 (k) (3))		
X	18.	User Fee Cover Sheet (Form FDA 3397)		
	19.	OTHER (Specify)		T
CERT	FICA	TION		
I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following: 1. Good manufacturing practice regulations in 21 CFR 210 and 211, 606, and/or 820. 2. Biological establishment standards in 21 CFR Part 600. 3. Labeling regulations in 21 CFR 201, 606, 610, 660 and/or 809. 4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR 202. 5. Regulations on making changes in application in 21 CFR 314.70, 314.71, 314.72, 314.99, and 601.12.				
6. Regulations on reports in 21 CFR 314.80, 314.81, 600.80, and 600.81. 7. Local, state and Federal environmental impact laws.				
		cation applies to a drug product that FDA has proposed for scheduling under the Contro	lied Substances A	at I agree not to market the
		il the Drug Enforcement Administration makes a final scheduling decision. Administration in this submission have been reviewed and, to the best of my knowledge	are certified to be	true and accurate
		willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.		
SIGNA	TURE	OF RESPONSIBLE OFFICIAL OR AGENT TYPED NAME AND TITLE	•	DATE
		Robert J. McCormack, Ph.D. Vice President, Regulatory Affairs		January 27, 2000
L)		Target Research Associates		
11	CR	bet 2011 (Abunack Cha)		_
		(1. 100 100 10		
		Vireet, City, State, and ZIP Code)	Telephone Number	•
Target Research Associates 554 Central Avenue (908) 464-7500		7500		
New Providence, NJ 079747				
		,		
,				
Public reporting burden for this collection of information is estimated to average 40 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:				
	ο-			

DHHS, Reports Clearance Officer
Paperwork Reduction Project (0910-0338)
Hubert H. Humphrey Building, Room 531-H
100 Independence Avenue, S.W.
Washington, DC 20201

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Number of Pages Redacted 9+12= 21



Confidential, Commercial Information

FILING MEETING PM CHECKLIST

NDA:

50-782 Clindagel (clindamycin phosphate ____ gel) 1%

Indication:

Once a day treatment of acne vulgaris

Sponsor:

Clindagel, LLC (US Agent: Target Research Associates)

Meeting:

March 6, 2000 9:00am

CDER Stamp Date:

January 27, 2000

Primary Goal Date (10 Month):

November 27, 2000

Secondary Goal Date (12 month):

December 27, 2000

Filing Date:

March 27, 2000

FILEABILITY: Initial overview of the NDA application:

PROJECT MANAGEMENT:

- 1. Do any of the following apply to this application (i.e., if YES, the application MUST BE REFUSED TO FILE under 314.101 (e) and there is no filing over protest):
 - a. Is the drug product already covered by an approved application? No.
 - b. Does the submission purport to be an abbreviated application under 314.55; however the drug product is not one for which FDA has made a finding that an abbreviated application is acceptable under 314.55(b)? No.
 - c. Is the drug product subject to licensing by FDA under the Public Service Act and Subchapter F of Chapter I of Title 21-of the CFR? No.
- 2. Do any of the following apply to this application (i.e., if NO, the application MAY BE REFUSED TO FILE under 314.101(d) and there is the potential for filing over protest):
 - a. Does the application contain a completed application form as required under 314.50 or 314.55? <u>Yes</u>.
 - b. On its face, does the application contain the sections of an application required by regulation and Center guidelines? <u>Yes.</u>
 - c. Has the applicant submitted a complete environmental assessment, which addresses each of the items, specified in the applicable format under 25.31 or has the applicant submitted evidence to establish that the product is under 25.24 of the CFR? <u>Volume 1.5</u>, page <u>26</u>.

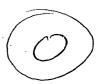
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THIS SECTION WAS DETERMINED NOT TO BE RELEASABLE

20 Pages



~		•
DATE	: August 23, 2000 11:30am	
APPLI	CATION NUMBER: NDA 50-782, Çiindagel 1% (clindamycin phosphate	— gel)
BETW	TEEN:	
-	Name: Jill Powers, Manager, Regulatory Affairs Andy Lawson	
	Phone: 908-464-7500	
• •	Representing: Target Research Associates for Clindagel, LLC	- ~
AND		•
	Name: Indira Kumar/Project Manager	
	Dennis Bashaw, Ph.D./Biopharm Team Leader	•
	Abi Adebowale, Ph.D./ Biopharm Reviewer	
	Lisa Mathis, M.D./Medical Reviewer	• *
	Division of Dermatologic and Dental Drug Products, HFD-540	
SUBJE	ECT: Clarification of the urinary excretion data	· ·
include	opharm reviewer wanted to clarify the treatment of the urinary excretion data ed in the submission for NDA 50-782 and, how the results were expressed in the second	· ·
the da concer forms	The Division noted that the amount excreted or the percentage of the interval (i.e. 24 hours in this case) is the standard way urinary data is usual that the Division is requesting. The Division indicated that the application of an aliquot of urine and that the volume of urine collected should and, these can then be used to obtain the amount excreted. The Division would provide tables and, how it was calculated.	lly reported. This is cant determined the be in the case report
•	oplicant representative noted that they would have to re-do the statistical test of go back to the data and convert concentration to amount of clindamycin in the	
The D	ivision inquired as to a timeframe when this data would be submitted for review	v.

The applicant representative stated that they would be in touch with the Division later today with a timeline.

Indira Kumar/Project Manager

Abimbola Adebowale, Ph.D./Biopharm Reviewer

BEST POSSIBLE COPY

DATE: August 17, 2000 11:45am

APPLICATION NUMBER: NDA 50-782, Clindagel 1% (clindamycin phosphate _____ gel)

BETWEEN:

Name: Jill Powers, Manager, Regulatory Affairs for Robert McCormack, Ph.D.

Phone: 908-464-7500

Representing: Target Research Associates for Clindagel, LLC

AND

Name: Indira Kumar/Project Manager
Abi Adebowale, Ph.D./ Biopharm Reviewer
Division of Dermatologic and Dental Drug Products, HFD-540

SUBJECT: Clarification of the urinary excretion data

The biopharm reviewer wanted clarification between the urinary excretion data submitted in the original submission, volume 1, page 14, Table 6 and the fax of 8-16-00. The biopharm reviewer was requesting a telecon between the biopharm scientist of Target Research & LLC and the FDA reviewers (Team leader and herself).

The applicant representative agreed to schedule a telecon and would get back to the FDA with available times on 8-18-00. She noted that if she had an answer by or before the telecon, she would send that to the Division as well.

/\$/

Indira Kumar/Project Manager

cc: Original NDA 50-782

HFD-540/Div. File

HFD-540/Indira Kumar/Project Manager

HHD-540/A. Adebowale/ D. Bashaw

APPEARS THIS WAS

TELECON

DATE: July 11, 2000 3:10pm

APPLICATION NUMBER: NDA 50-782, Clindagel 1% (clindamycin phosphate — gel)

BETWEEN:

Name: Jill Powers, Manager, Regulatory Affairs for Robert McCormack, Ph.D.

Phone: 908-464-7500

Representing: Target Research Associates for Clindagel, LLC

AND

Name: Indira Kumar/Project Manager
Abi Adebowale, Ph.D./ Biopharm Reviewer
Division of Dermatologic and Dental Drug Products, HFD-540

SUBJECT: Information request for Biopharm

The biopharm reviewer requested a table of the pharmacokinetic variable/AUC for each patient for urine and plasma that was used in the statistical analysis for both clindamycin and cleocin.

The sponsor representative said that she would submit the information in both electronic and paper format as soon as possible.

/S/

Indira Kumar/Project Manager

cc: Original NDA 50-782 HFD-540/Div. File HFD-540/Indira Kumar/Project Manager HFD-540/A. Adebowale

TELECON

APPEARS THIS WAY ON ORIGINAL

DATE: March 30, 2000 2:00 pm

APPLICATION NUMBER: NDA 50-782, Clindagel 1% (clindamycin phosphate _____ gel)

BETWEEN:

Name: Jill Powers, Manager, Regulatory Affairs for Robert McCormack, Ph.D.

Phone: 908-464-7500

Representing: Target Research Associates for Clindagel, LLC

AND

Name: Indira Kumar/Project Manager

Division of Dermatologic and Dental Drug Products, HFD-540

SUBJECT: Electronic data clarification.

Statistical:

SAS data sets, programs (SAS version 6.12), transport files are okay.

Sponsor representative sent data 3/24/00

The format the Pharmacology/ Dermal carcinogenicity data should be in SAS data, transport files, analysis and a Word description of the data.

The sponsor representative said that she was planning to submit that data in that format.

/\$/

Indira Kumar/Project Manager

cc: Original NDA 50-782
HFD-540/Div. File
HFD-540/Indira Kumar/Project Manager

APPEARS THIS WAY ON ORIGINAL

TELECON

DATE: March 21, 2000 9:40am

APPLICATION NUMBER: NDA 50-782, Clindagel 1% (clindamycin phosphate — gel)

BETWEEN:

Name: Jill Powers, Manager, Regulatory Affairs for Robert McCormack, Ph.D.

Phone: 908-464-7500

Representing: Target Research Associates for Clindagel, LLC

AND

Name: Indira Kumar/Project Manager

Division of Dermatologic and Dental Drug Products, HFD-540

SUBJECT: NDA number and electronic data.

The Division wanted to inform the company that the NDA number has changed from to 50-782 because this product is an antibiotic approved prior to FDAMA therefore it retains the 50K number series.

There were several requests for electronic data sets from several reviewers per the filing meeting:

Statistical:

SAS data sets, programs (SAS version 6.12), and "Clinical Data summary and results of the statistical analysis" in electronic format (Microsoft Word).

Also the Final Study Report of the Phase 3 study in electronic format (Microsoft Word).

Pharmacology/Toxicology:

Dermal carcinogenicity data and analysis electronically by the end of March.

The sponsor representative can get us the Statistical data by the week of March 27, 2000 and the Pharmacology data by the week of April 10, 2000.

PM to follow up on exactly what format should the Pharmacology/ Dermal carcinogenicity data be in.

/\$/

Indira Kumar/Project Manager

DATE: 2-1-00 1:25am, 3:40pm

APPLICATION NUMBER: NDA ——— Clindagel 1% (clindamycin phosphate —

gel)

BETWEEN:

Name: Jill Powers, Manager, Regulatory Affairs for Robert McCormack, Ph.D.

Phone: 908-464-7500

Representing: Target Research Associates for Clindagel, LLC

AND

Name: Indira Kumar/Project Manager

Division of Dermatologic and Dental Drug Products, HFD-540

SUBJECT: User Fee Payment

The Division wanted to know if the user fee was paid and when.

The sponsor representative noted that the user fee should have been wired January 18 or 19, 2000. She will verify with Clindagel, LLC in California today at 11:00am and contact the Division as soon as she has word of the funds.

She also verified that the Division, last week, received 15 desk copies of the 1.1 volume of the NDA.

I introduced myself as the Project Manager of this new NDA and asked that all communications go through me.

3:40pm

Jill Powers called to follow up on the User Fee issue. She noted that Clindagel, LLC wired the funds January 28, 2000 and the confirmation number is — She will be faxing this information to the Division today.

/S/

2-1-00

Indira Kumar/Project Manager

cc: Original NDA

HFD-540/Div. File

HFD-540/Indira Kumar/Project Manager

TELECON

PEDIATRIC PAGE

(Complete for all original applications and all efficacy supplements)

w Pediatric Page must be completed at the time of each action even though one was pre

MOIL. A Hem I ediadic I a	ge must be completed at the time of	each acaon even alough one was pr	epared at the time of the last acticit.
NDA/PLA/PMA #50-782	Supplement #	Circle one: SE1 SE2 SE3 SE4 SE5 S	E 6
-540 Trade and g	eneric names/dosage form: <u>Clindagel (</u>	clindamycin phosphate) topical gel, 1%	Action: AP AE NA
Applicant Clindagel, LLC (T	arget Research Associates)	Therapeutic Class	38
Indication(s) previously appre	oved Treatment of acne vulgaris		
Pediatric information in label	ing of approved indication(s) is adequat	e X inadequate	
Proposed indication in this a	pplication Treatment of acne vulgaris		
FOR SUPPLEMENTS, ANS	WER THE FOLLOWING QUESTIONS I	N RELATION TO THE PROPOSED IN	DICATION.
WHAT PEDIATRIC AGE G	ANY PEDIATRIC AGE GROUPS? _X_ ROUPS IS THE DRUG NEEDED? (Che nonth)Infants (1month-2yrs)	eck all that apply)	cents(12-16yrs)
	• - •		nation has been submitted in this or beling for all pediatric age groups. Further
applications and has	NG IS ADEQUATE FOR <u>CERTAIN</u> AGI been adequately summarized in the labor ents but not neonates). Further informations	eling to permit satisfactory labeling for	as been submitted in this or previous certain pediatric age groups (e.g., infants,
this use. a. A new dosing fb. A new dosing fc. The applicant I(1) Stud(2) Prote(3) Prote(4) If no	ormulation is needed, and applicant has ormulation is needed, however the sport has committed to doing such studies as lies are ongoing, ocols were submitted and approved. ocols were submitted and are under review protocol has been submitted, attach me is not willing to do pediatric studies, attach	s agreed to provide the appropriate formsor is either not willing to provide it or will be required. iew. emo describing status of discussions.	
· · · · · · · · · · · · · · · · · · ·	S ARE NOT NEEDED. The drug/biologic	ic product has little potential for use in p	pediatric patients. Attach memo explaining
5. If none of the above	apply, attach an explanation, as neces	sary.	
	RIC PHASE IV COMMITMENTS IN THE N FOR ANY OF THE FOREGOING ITE		No ·
This page was completed ba	sed en information from X (Medical Rev	new/Medical Team Leader (e.g., medi	cal review, medical officer, team leader).
Jonathan K. Wilkin, M.D./Div	rision Director. HFD-540	Date	<u>69</u>
Indira Kumar/ Regulatory Pr		Date	
Archival NDA _ HFD-540/Wilkin/Kum HFD-104/Peds/T.Cre	, :HFD-540/Div File ar/Artion Package	e e e e e e e e e e e e e e e e e e e	(revised 3/6/00)

Pediatric Use Information

In accordance with 21 CFR 314.55(c)(2)(ii) we are hereby requesting a full waiver from supplying Pediatric Use Information for Clindagel in the treatment of acne. A full waiver is being requested since the number of patients available with pediatric acne is so small, it makes the necessary studies highly impractical to conduct in a reasonable period of time.

Gordon Dow, PharmD

Clindagel, LLC

APPEARS THIS WAY ON ORIGINAL